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Radiographic Outcome and Complication Rate of 34 Graduates After Treatment With Vertical Expandable Prosthetic Titanium Rib (VEPTR): A Single Center Report

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Background: The final strategy for graduates from growth-sparing surgery is challenging. The purpose of this study was to evaluate the radiographic outcome and complications of patients with early onset scoliosis (EOS) who have graduated from vertical expandable prosthetic titanium rib (VEPTR) treatment, either undergoing final fusion surgery or following a nonfusion approach.

Methods: Final treatment for VEPTR graduates was divided in "VEPTR in situ without final fusion," "removal of VEPTR without final fusion," and "removal of VEPTR with instrumented final fusion." Radiographic evaluations included main coronal Cobb angle and main kyphosis pre and post VEPTR implantation, at the end of implant lengthening, after final fusion (if applicable), and at latest follow-up. Complications during VEPTR treatment and in case of final fusion were reported.

Results: In total, 34 VEPTR graduates were included; 17 underwent final fusion surgery, and 17 followed a nonfusion strategy. Average coronal Cobb angle before VEPTR implantation was 70 ± 23 degrees (range, 21 to 121 degrees), and 65 ± 22 degrees (range, 17 to 119 degrees) at latest follow-up. Average main kyphosis angle was 53 ± 27 degrees (range, 6 to 137 degrees) before VEPTR, and 69 ± 34 degrees (range, 10 to 150 degrees) at latest follow-up. There was a 41% complication rate with final fusion surgery.

Conclusions: There is a high complication rate during VEPTR treatment and with final fusion surgery. The stiffness of the spine and thorax allow for only limited correction when performing a final instrumented spondylodesis. Avoiding final fusion may be a viable alternative in case of good coronal and sagittal alignment.

Level of Evidence: Level IV—therapeutic.

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The authors declare no conflicts of interest.

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DOI: 10.1097/BPO.0000000000001338

Key Words: early onset scoliosis, spinal fusion, growth-sparing surgery

(*J Pediatr Orthop* 2019;39:e731–e736)

Over the past 3 decades different growth-sparing surgical techniques have emerged, replacing the habit of early operative spinal fusion in patients with early onset scoliosis (EOS). According to the classification of growth sparing implants provided by Skaggs et al,[1] the use of distraction-based systems has been favored, focusing on optimizing pulmonary development by controlling the spinal deformity and stimulating the growth of the spine, thorax and lungs.[2,3] Although, there is current consensus to use bilateral spine-based implants such as traditional (tGR) or magnetically controlled growing rods (MCGR) in case of absence of thoracic insufficiency syndrome (TIS), the use of rib-based implants appeared attractive with the introduction of the vertical expandable prosthetic titanium rib (VEPTR) technique. This approach allows for indirect spine-sparing control of deformities.[4–7] This initial enthusiasm continuously declined with the number of studies reporting on high complication rates as well as ossifications along the implant and across ribs, even in case of a formerly normal thorax.[8–11] For these reasons, the use of VEPTR should be limited to the indications directed by the inventor, Dr. Robert Campbell Jr, namely for patients with congenital EOS and/or in case of TIS.

Despite many reports on growth friendly implants, there is paucity of description regarding the final strategy for EOS patients at the end of growth. Flynn et al[12] in 2013 were the first ones to report on a multicenter series of 99 graduates from growing rod (GR) treatment. Two other reports from the Growing Spine Study Group (GSSG) focused on EOS patients after tGR[13] and Shilla growth guidance treatment,[14] the former focusing on the possibility of avoiding final surgical fusion. Johnston et al[15] reported on functional and radiographic outcomes of 12 patients following growth sparing management, including one VEPTR patient, and Sawyer et al[16] looked at complications and radiographic outcomes of 37 patients after distraction-based treatment, whereof 32 had rib-based fixation without specification of the type of implant. To determine the incidence and causes of reoperations after final fusion, Poe-Kochert et al[17] reported on 100

patients with a minimum follow-up of 2 years for tGR graduates after final fusion surgery. A recent study focusing on the decision-making process of EOS graduates included 23 tGR and 5 VEPTR patients,[18] and Lattig et al[19] reported on a case series of 5 VEPTR graduates. To our knowledge our study represents the largest cohort of patients after growth sparing treatment with VEPTR.

The aim of this study was to gain additional information on how to configure the final treatment strategy for EOS patients who have graduated from VEPTR treatment. Scaling down the knowledge gap of when to stop growth sparing treatment and decide on performing or avoiding final fusion surgery should further improve the quality of care in this challenging field of pediatric orthopaedics.

METHODS

After getting approval from the institutional ethical review board, the hospital's surgical database was screened for all EOS patients treated with VEPTR. Patients were excluded in case of incomplete medical records or ongoing growth sparing treatment. The etiology of the deformity was classified using the C-EOS classification.[20] Final treatment was divided in "VEPTR in situ without final fusion," "removal of VEPTR without final fusion," and "removal of VEPTR with final instrumented fusion." Patients who had undergone final fusion surgery were further subdivided in case of use of preoperative halo-gravity traction. Radiographic measures included major curve's Cobb angle and main kyphosis assessment pre and post VEPTR implantation, at the end of implant lengthening, after final fusion surgery (if applicable), as well as at latest follow-up. In case of preoperative halo-gravity traction before final fusion, the major curve's Cobb angle and the main kyphosis at the end of the traction period were also documented. Complications during VEPTR treatment and in case of final fusion surgery were classified as implant-related, infections, and others. The severity of the complications was classified as proposed by Smith et al.[21] In addition, age at VEPTR implantation, duration of VEPTR treatment, number of lengthenings, as well as the length of follow-up was documented.

Statistics

Data are presented as the mean ± SD together with its range; from its minimum to its maximum value. Measurements were compared with unpaired *t* tests when normally distributed. The Wilcoxon signed rank-sum test was used to compare non-normally distributed variables. Shapiro-Wilk tests were used to verify a normal distribution of samples. *P*-values were 2-sided, and $P = 0.05$ was considered the threshold for statistical significance. All statistical analyses were performed using the open-source statistical package R (http://www.r-project.org/).

RESULTS

Between April 2002 and June 2013, 55 patients underwent VEPTR instrumentation for EOS at our institution; 21 patients had to be excluded; 11 patients are still under growth sparing treatment, and 10 patients had incomplete medical records (3 died during the lengthening period because of their comorbidities, 6 foreign patients had further treatment in their home country, and one patient had a VEPTR inserted as a salvage procedure). In total, 34 VEPTR patients had graduated from growth sparing treatment and were eligible for evaluation. Demographics and etiologies of VEPTR graduates are listed in Table 1. In 4 patients, the index operation was performed after the age of 10. All of them had a congenital etiology of scoliosis diagnosed before the age of 10. With intended 6-monthly intervals a total of 347 implant lengthenings were performed.

TABLE 1. Etiologies and Demographics of Patients Graduated From VEPTR Treatment

	Male	Female	Total
VEPTR graduates	19	15	34
Etiology of EOS			
Idiopathic	1	0	1
Neuromuscular	4	5	9
Congenital	11	7	18
Syndromic	1	3	4
Thoracogenic	2	0	2
Age at VEPTR implantation (y)			
Average	7.9	6.8	7.4
Minimum	3.3	1.7	1.7
Maximum	13.5	11.6	13.5
Duration of VEPTR treatment (y)			
Average	6.5	6.8	6.7
Minimum	2.3	3.5	2.3
Maximum	10.8	10.5	10.8
No. lengthenings			
Average	10	11	10
Minimum	4	5	4
Maximum	16	21	21

EOS indicates early onset scoliosis; VEPTR, vertical expandable prosthetic titanium rib.

The mean age at the end of VEPTR treatment was 13.8 ± 2.3 years (range, 9.6 to 19.6 y). The mean time between the last VEPTR lengthening and the latest follow-up was 50 ± 25 months (range, 10 to 115 mo).The main coronal Cobb angle before the index operation averaged 70 ± 23 degrees (range, 21 to 121 degrees), reducing to 50 ± 22 degrees (range, 10 to 107 degrees) after VEPTR implantation, and being 65 ± 22 degrees (range, 17 to 119 degrees) after the last lengthening (Fig. 1). The main kyphosis averaged 53 ± 27 degrees (range, 6 to 137 degrees) preoperative, changing to 43 ± 23 degrees (range, 5 to 95 degrees) immediately postoperative, and 70 ± 33 degrees (range, 15 to 133 degrees) after the last lengthening.

17 VEPTR graduates followed a nonfusion final strategy. In 5 patients with congenital EOS and unilateral constructs the implants were simply removed. Their mean follow-up period was 39 ± 16 months (range, 19 mo to 59 mo). The average major curve and kyphosis angles at the end of lengthening for this group were 54 degrees and 50 degrees Cobb angle, respectively. In 12 patients the VEPTR was left in situ. The mean follow-up for this group was 43 ± 25 months

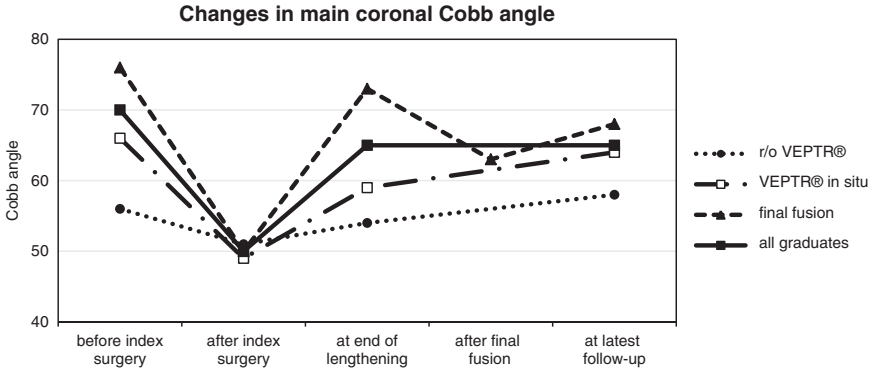

FIGURE 1. Changes in main coronal Cobb angle after vertical prosthetic titanium rib prosthesis (VEPTR) implantation (= index surgery), at the end of implant lengthening, after final fusion (if applicable), and at latest follow-up for all VEPTR graduates (continuous line), and dependent on final treatment strategy (discontinuous lines).

(range, 10 mo to 87 mo) with an average major curve's Cobb angle of 59 degrees and an average main kyphosis of 58 degrees. Final fusion surgery was recommended in 2 of the 12 patients, but after interdisciplinary assessment the patients were not eligible for surgery because of their severely restricted cardiopulmonary comorbidities. Main kyphosis angle at the end of lengthening until latest follow-up did not change in patients following a nonfusion strategy ($P = 0.473$). The major curve showed some minor, statistically not significant progression in both, patients with removal of VEPTR ($P = 0.289$), and patients with VEPTR in situ ($P = 0.051$) (Figs. 1, 2). No hardware failure occurred in patients following a nonfusion strategy. Seventeen patients underwent instrumented final fusion surgery. The mean age at the time of final fusion was 14.6 ± 1.5 years (range, 11.1 y to 16.7 y), with a mean interval of 2.1 ± 1.1 years (range, 0.6 y to 4.1 y) between the last lengthening and the final spondylodesis. Compared with the nonfusion group, patients undergoing final fusion surgery had significantly higher average major curve Cobb angle (73 vs. 57 degrees; $P = 0.04$) and main kyphosis angle (85 vs. 54 degrees; $P = 0.05$) at the end of lengthening, and they were significantly younger at the time of VEPTR implantation (6.2 y vs. 8.7 y; $P = 0.005$) (Fig. 3). With final fusion surgery an average 14% correction rate of the main coronal deformity was achieved, but significant ($P = 0.034$) loss of correction was present after a mean follow-up of 31 months (Fig. 1), although, no obvious implant loosening or breakage appeared. Average main kyphosis correction rate was only 9% and, although not statistically significant ($P = 0.085$), some loss of correction was also noted at the latest follow-up (Fig. 2). An analysis of the subgroups showed that the loss of correction was tendentially higher in patients with preoperative halo-gravity traction.

Nine patients had one-staged removal of VEPTR and instrumented spinal fusion surgery. Eight patients had a staged procedure with VEPTR removal followed by halo-gravity traction and final instrumented spondylodesis. The average duration of halo-gravity traction was 27 ± 11 days (range, 14 to 43 d), and the mean correction of the main coronal Cobb angle and the main kyphosis was 11 ± 5 degrees (range, 1 to 18 degrees; $P = 0.631$) and 12 ± 6 degrees (range, 2 to 21 degrees; $P = 0.124$), respectively.

Overall, 65 complications occurred during VEPTR treatment, leading to a total of 40 unplanned returns to the operating room (OR). This corresponds to a mean complication rate of 1.9 per patient or 0.2 per elective lengthening.

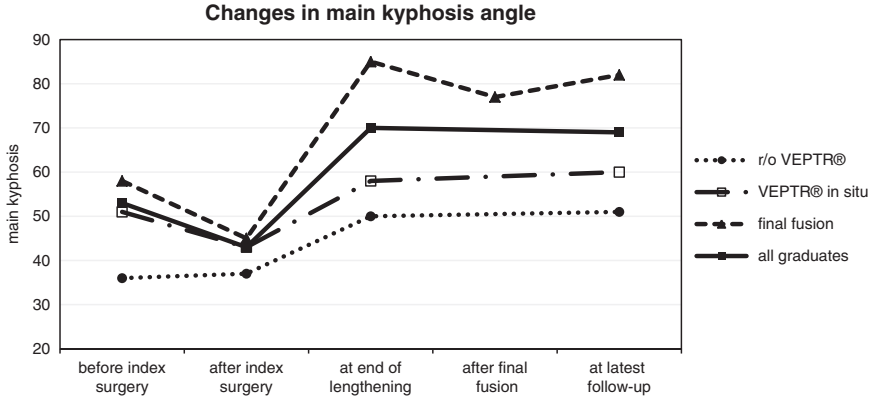

FIGURE 2. Changes in main kyphosis angle after vertical prosthetic titanium rib prosthesis (VEPTR) implantation (= index surgery), at the end of implant lengthening, after final fusion (if applicable), and at latest follow-up for all VEPTR graduates (continuous line), and dependent on final treatment strategy (discontinuous lines).

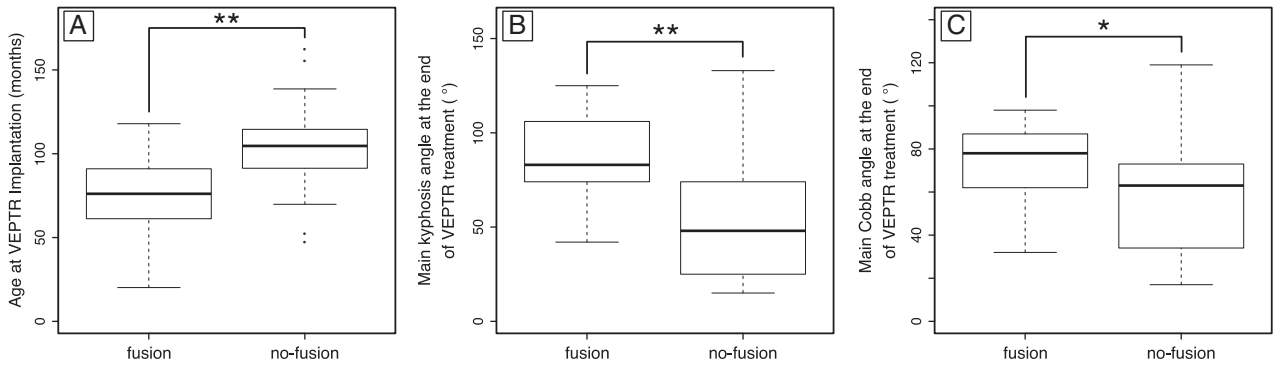

FIGURE 3. Parameters that reached statistical significance between patients undergoing final fusion surgery and patients following a nonfusion strategy at the end of VEPTR (vertical expandable prosthetic titanium rib) treatment.

According to the classification system by Smith et al,[21] 32 complications could be rated as severity grade (SV) I, not requiring unplanned surgery, 27 complications were SV IIa requiring a single unplanned trip to the OR, and 6 complications were SV IIb requiring multiple unplanned surgeries. Basically, the 3 patients who were excluded because they died during VEPTR treatment should be rated as SV IV. Forty-five of the 65 (69%) complications were implant-related, representing failure of anchorage (ie, dislocation of the rib hook) in 91% and rod breakage in 9%; 19 surgical site infections (SSI) occurred in 11 patients. The overall infection rate during growth sparing treatment was 5.0% (19 infections/381 surgeries, including index operations).

Greater main kyphosis before VEPTR implantation was the only parameter to show statistically significant correlation ($P < 0.001$) to a higher number of complications.

There was a 41% (7/17) complication rate in patients with final fusion leading to 6 unplanned returns to the OR, (35% reoperations). Two patients sustained an implant-related early SSI (within 2 wk final fusion surgery), requiring one additional surgery each, and antibiotic treatment. In 2 patients with proximal junctional kyphosis the instrumentation was extended cranially. One Goldenhar syndrome patient with a postoperative loss of sagittal balance underwent a single level pedicle subtraction osteotomy and extension of the fixation to the pelvis 9 months after final fusion (Fig. 4). In one patient final fusion surgery had to be interrupted because of a malfunction of the ventricular-peritoneal shunt system. One patient with extensive superficial delayed wound healing did not require additional surgery.

DISCUSSION

Surgical treatment of EOS represents a challenge for the patient and his family, as well as for the treating physician. Apart from the high complication rate and the psychosocial burden of repetitive hospital stays and surgeries, the evolution of the deformity is difficult to predict. The same applies when it comes to decide on final treatment regimen. Which patients are eligible for a nonfusion strategy, and which patients should undergo final fusion surgery? What is the best moment to cease growth sparing treatment? The paucity of reliable data and the heterogeneity of EOS patients harden the decision-making process, and comorbidities, high complication and reoperation rates, as well as each individual patient's and families' expectations must be respected when developing the final treatment plan.

Most of the time the decision about when to stop expansions is less surgeon-driven, but rather determined by curve progression, failure to further distract, or complications.[18,22] Following the progressive natural history of adolescent idiopathic scoliosis (AIS) with curve magnitudes of >40 to 50 degrees Cobb angle at skeletal maturity,[23] the magnitude of the deformity is likely to be the most important factor to indicate a definitive spinal fusion in EOS graduates. This is reflected in our patients and is in consistence with a recent report by Pizones et al[18] who stated that performing posterior spinal fusion depends on unacceptable or progressive major curve deformity, sagittal misalignment, or complications with previous implants. Whether or not the etiology of the EOS plays a role is debatable. In our cohort, only 30% of the patients with congenital EOS underwent final fusion surgery compared to 79% of noncongenital EOS patients. Other studies also showed higher rates of final instrumented spondylodesis for patients with noncongenital EOS,[12,14,16] but this could not be confirmed by Pizones et al[18] who reported that patients suffering from congenital EOS were more likely to undergo posterior spinal fusion surgery.

Staged surgery with halo-gravity traction prior to final fusion was rather dependent on the degree of kyphosis than coronal plane deformity. To our knowledge, none of the available articles on EOS graduates provide further information on the use of halo-gravity traction before performing final fusion surgery. Looking at the little corrections achieved in our patients, and considering the huge psychologic and economic impact, the effectiveness of preoperative halo-gravity traction must be questioned. We assume that beside the occurrence of spontaneous fusions of the spine with distraction-based implants,[24] the use of rib-based implants with additional ossifications of the thorax and along the implants, as shown in a multicenter study including our own patients,[9] may further explain the low correction potential of

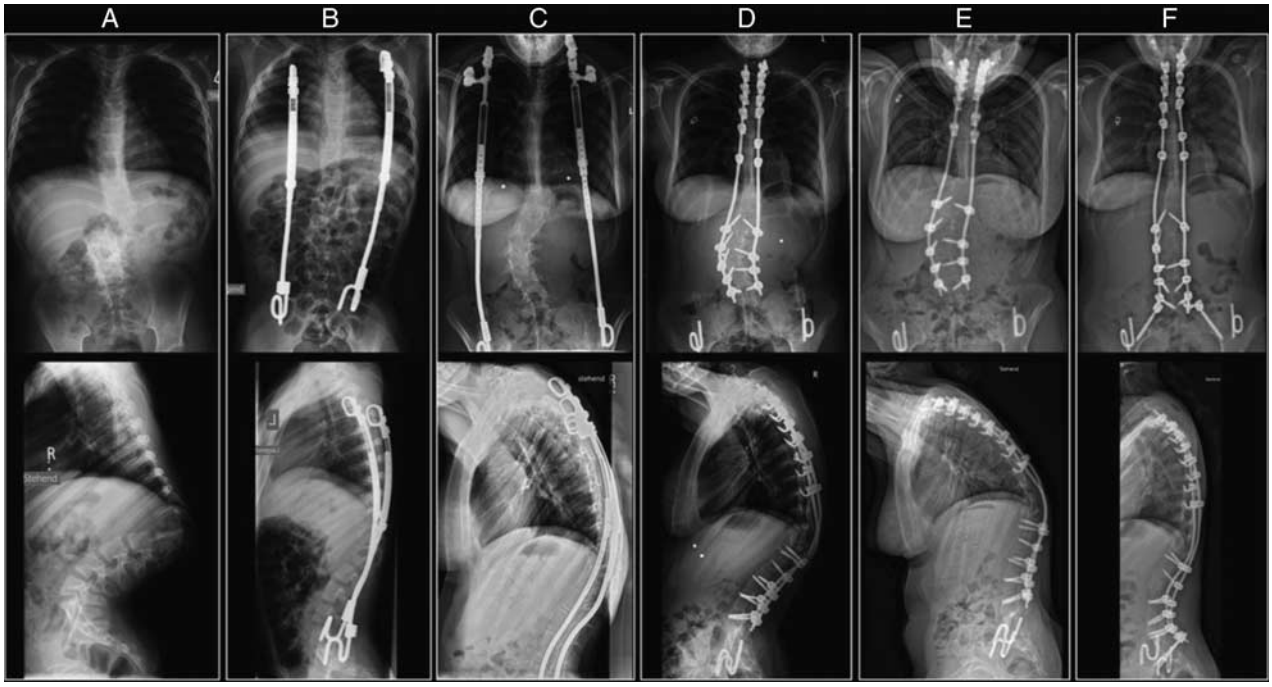

FIGURE 4. Course of an ambulant patient with a Goldenhar syndrome and a syndrome-related early onset scoliosis (EOS). Severe thoracolumbar kyphoscoliosis before VEPTR implantation (A) could be significantly improved after the index surgery (B), and the correction was largely maintained at the end of implant lengthening (C). One-staged final fusion surgery was performed with removal of VEPTR and instrumented spondylodesis from T2 to L5 (D). The alar hooks of the former caudad VEPTR foundation were left in situ because of relevant sinking in the ilium. At the 6-month follow-up the patient presented with marked loss of sagittal balance requiring revision surgery (E). Sagittal balance was restored by performing a pedicle subtraction osteotomy at L3 and extending the distal foundation to the pelvis (F).

halo-gravity traction in our graduates. Bacterial implant colonization, which can be present in up to 47% of VEPTR patients because of repetitive surgical implant lengthening can be another reason for choosing a staged final fusion procedure.[25]

In contrast to "late-onset" pediatric scoliosis surgery with generally very good deformity correction, the ability to further correct the spine at the end of growth sparing surgery is limited. Altered vertebral anatomy with poor bone quality because of year-long implant-related stress-shielding,[26] in combination with poorly perfused scar tissue and stiff high-grade deformities are the consequences of repetitive surgical lengthening procedures, making final instrumented fusion surgery in these patients highly demanding. In 62% of the growing rod graduates reported by Flynn et al[12] the spine was described as completely stiff, allowing for $>50\%$ deformity correction in only 15% of patients. This is consistent with other authors, reporting on a high degree of rigidity, spontaneous autofusion, and no significant changes with final fusion surgery.[16,19] The observed loss of correction after final fusion, which was particularly evident in patients with prior halo-gravity traction, has not been described in other studies. The extent to which this can be attributed to a settling of the bone graft in the absence of any indications for implant loosening cannot be conclusively assessed. Beside the limited deformity correction, everyone, including the patient and parents, must be aware of the high complication and reoperation rates after final instrumented spondylodesis. Whereas 6 of 17 (35%) of our final fusion patients underwent revision surgery, other authors reported on 20% to 24% of patients requiring additional surgical procedures after posterior instrumented spinal fusion.[16,17] With a mean time to the first reoperation after the final fusion procedure of 2.0 years in the cohort of Poe-Kochert et al,[17] the complication rate of our patients is likely to increase with only 8 of 17 of them having reached a minimum 2-year follow-up yet.

The considerable complication rate and the encounter of rigid deformities of the spine and the thorax demand to contemplate the avoidance of final fusion procedures. According to Jain et al,[13] the most common indications for forgoing final surgical fusion in growing rod graduates were satisfactory axial alignment and balance, no implant-related problems, and minimal gain in length at the last distraction. But, as with our patients, there is a lack of mid-term and long-term follow-up of graduates without final fusion and it is likely that some of these patients will require additional surgery in the future.

Although, this is the largest single-center series reporting on VEPTR graduates, the study shares the limitations of retrospective data analysis. Future investigations should as well focus on patient- or proxy-reported outcome, especially in regard of health-related quality of life, which

might be of greater importance to each individual patient than basic radiographic parameters.

CONCLUSIONS

Despite an increasing body of knowledge on graduates from growth sparing surgical treatment, the final strategy remains controversial and difficult. Age at the time of index surgery, the severity of the deformity at the end of growth sparing treatment, as well as coronal and sagittal alignment appear to be important factors to decide on performing final fusion surgery or not. The limited ability to further correct the deformity and the high rate of complications and reoperations after instrumented spondylodesis must be considered and matched with each individual patient's expectations, and everyone must be aware that the "final" fusion might not be fruitful nor the last surgery. Therefore, the avoidance of final surgical fusion may represent a viable alternative for some more moderate forms of EOS. Longer follow-up is needed to report on the natural history of unfused EOS graduates before recommending this option.

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